



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Golds et al.

Examiner: Ho, U.

Serial No.: 10/716,639

Group Art Unit: 3738

Filed: November 19, 2003

Docket: 760-57RCE/CON

For: MESH AND STENT FOR
INCREASED FLEXIBILITY

Dated: December 23, 2004

I hereby certify this correspondence is being deposited with
United States Postal Service as first class mail, postpaid in an
envelope, addressed to: Commissioner for Patents, P.O. Box 1450,
Alexandria, VA 22313-1450 on December 29, 2004.

Signature Kim Tillman/ Kim Tillman

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES TO
OVERCOME A PATENT UNDER 37 C.F.R. §1.131

Sir:

1. I, Ellen Golds, a citizen of the United States, residing at 32 South Dr., Hastings-on-Hudson, New York, am the inventor of the above-identified application.

2. At the time of the invention thereof, I was an employee of Boston Scientific. The present application was assigned to Scimed Life Systems Inc. a subsidiary of Boston Scientific. I submit this Declaration to establish completion of the invention set forth in this application in the United States at a date prior to February 2, 1999, i.e. the effective date of U.S. Patent No. 6,398,803; to Layne et. al. (hereinafter the '803 patent) which was cited by the Examiner in an Office Action mailed December 17, 2002.

3. From the documents submitted herewith, and as set forth hereinbelow, it can be seen that the invention was completed in the United States before February 2, 1999, which is a date earlier than the U.S. filing date of the '803 patent. Completion of the invention prior to February 2,

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1999 is shown by conception and actual reduction to practice of the invention as evidenced by prototypes, which were made in accordance with the claimed invention.

4. To establish conception and reduction to practice, i.e. completion of the invention at a date prior to February 2, 1999, the following documents are being submitted as evidence:

A. Meadox, Boston Scientific Corporation Invention Disclosure Pages 1-3 (Exhibit A) bearing a date signed by the inventor and a date signed by a witness prior to February 2, 1999, the earliest effective filing date of the '803 patent. The Invention Disclosure describes the conception of the device according to the claimed invention and a method of making same.

B. Meadox, Boston Scientific Corporation laboratory notebook pages 2, 7, 9-11; Book No. SA4, (Exhibit B) bearing a date signed by the inventor and a date signed by a witness prior to February 2, 1999, the earliest effective filing date of the '803 patent. The notebook page describes the claimed invention and method of making same. Additionally, experimental results for the actual reduction to practice of the claimed device describing the actual existence of the device in question, sufficient to work for its intended purpose.

5. The material submitted herewith establishes that the invention was complete, i.e. conceive and reduced to practice at a date prior to February 2, 1999, the filing date of the '803 patent.

6. This Declaration is submitted in response to an Office Action and is therefore believed to be timely filed.

7. I hereby declare that all statements made herein of my own knowledge are true and that

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all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED: December 23, 2004



Ellen Golds

INVENTOR NAMES
Please include full address on back

Jeff Boatman, David Tseng, Ellen Golds

LOCATION

Meadox Medicals

EXT

738

DATE

BEST AVAILABLE COPY

1. Appropriate Title of Invention:

Mesh ePTFE covering of endovascular stent grafts: methods to expose the stent knuckles

2. Summarize the device, method or process of the invention:

This invention describes methods how to expose the stent knuckles during ePTFE laminating of endovascular stent grafts. Three methods could be used to expose the knuckles:

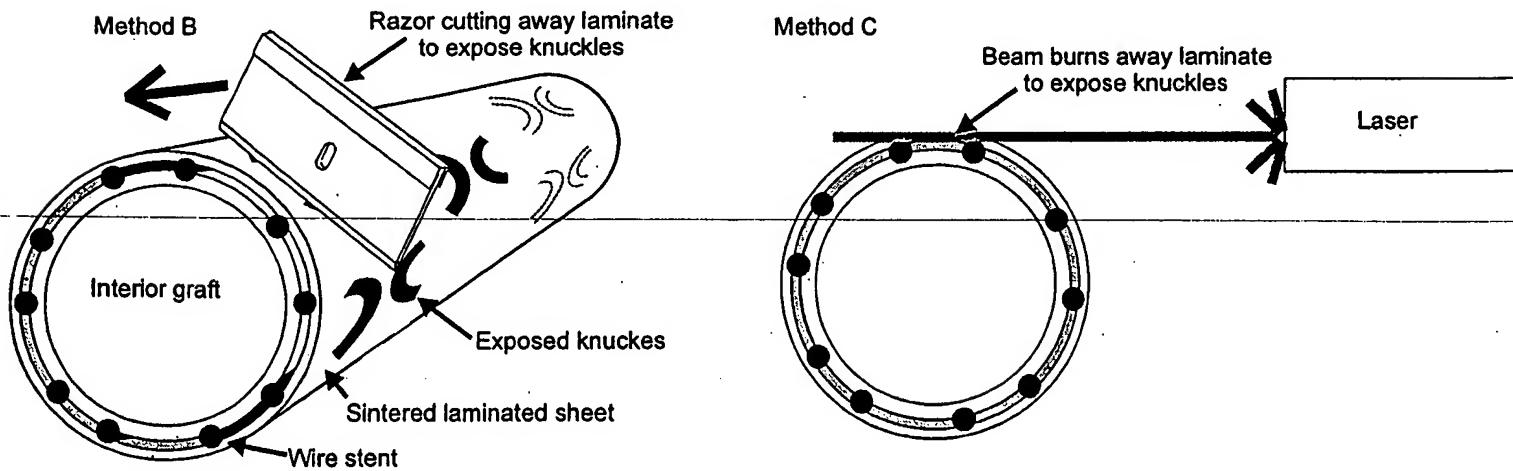
- A) After wrapping two layers of PTFE sheet on stent, a razor blade was used to slice the PTFE covering on the knuckles (1 mm length of opening), use razor blade to pull material back over bend, lift the knuckle, and insert the PTFE material under the stent knuckles. After knuckles were exposed, the stent graft assembly was sintered under sintering temperature.
- B) After stent graft assembly was sintered under 680°F temperature, a razor blade was used to scrape the PTFE covering out of knuckles. Then re-sinter the stent graft assembly under 680°F.
- C) Use a cutting laser beam to cut PTFE material around the stent knuckles. Then a non-cutting tool could lift the knuckle up and insert the PTFE material underneath.

3. Briefly describe the advantage of this invention:

Using mesh ePTFE covering on stent grafts give stent grafts more flexibility as compared to total covered stent graft. The exposed knuckles allow more freedom of movement.

The methods described here are easy to operate, easy to scale up, and less time consuming than previous methods.

4. Sketch the invention:



(Method A not shown; similar to Method B except perform before sintering)

Meadox®
 Boston Scientific Corporation

R. Boatman
David Tseng
Ellen Golds

Witness:
 Read & Understood

Patricia A. Murphy
 Dated: 6/10/04

INVENTION DISCLOSURE

5. What is the development stage of this invention (check all that apply)?

Conceptual/Unwritten
 Lab Book
 Verbally Disclosed In house Out of house
 Written Disclosure or Report In house Out of house
 Prototype or Empirical Experience
 Bench Animal Clinical
 Actual Product, Method or Process

6. What is the current project phase?

None; not an approved product Development
 Definition Manufacturing Scale-up
 Design

 Product/To be released: Date Europe Q4'98; U.S. 2000
 Product Released: Date _____

Please indicate the product name and number, if available:

7. Which division is sponsoring this project?

Medi-Tech Maple Grove
 Microvasive Endo Meadowx Medicals
 Microvasive Uro Sunnyvale
 Other _____

Name the marketing/engineering manager(s) championing this invention: Ellen Golds

8. Name any key physicians interested in this invention: N/A

9. Describe any alternate embodiments or further features that could be included with this invention. If you think that the invention could be useful for other projects or divisions, please indicate so.

Meadox
Boston Scientific Corporation

Witness:
Read & Understood

Patricia A. Murphy
C
Dated: _____

10. Indicate/attach any prior art that you are aware of (please include Boston Scientific work):

A prior invention disclosure about mesh ePTFE covering of stent graft was submitted by Ellen Golds et al.

Thank you for your completed invention disclosure. Please be sure to have the disclosure witnessed by a person who understands the invention, yet who is not an inventor or involved directly with the project. Please attach any notes, samples, specifications, drawings and prior art that may assist in the development of a patent application. Your disclosure will be reviewed by the appropriate Patent Review Board and you will be notified as to the decision to pursue or further develop this invention.

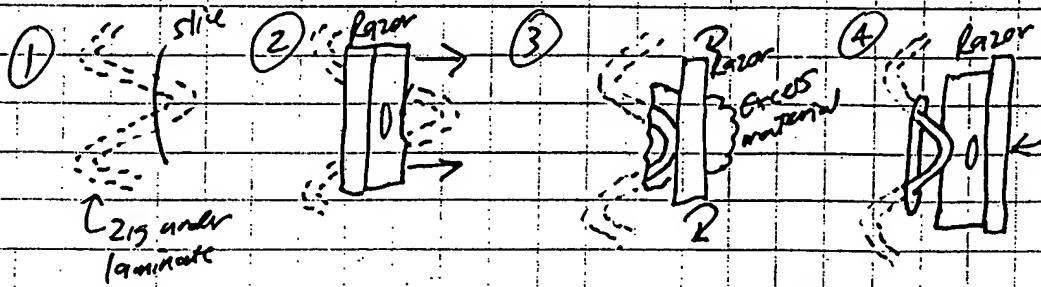
Meadox®
Boston Scientific Corporation

Witness:
Read & Understood

Patricia A. Murphy
Dated: _____ C

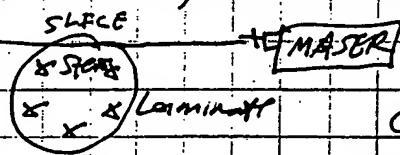
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Based on concept by D. Tseng. Wrap stent with two layers of laminating material, then slice material perpendicular to stent about 1mm below bend. Use razor to pull material back over bend, lift zig up enough so that material will slide back under zig.



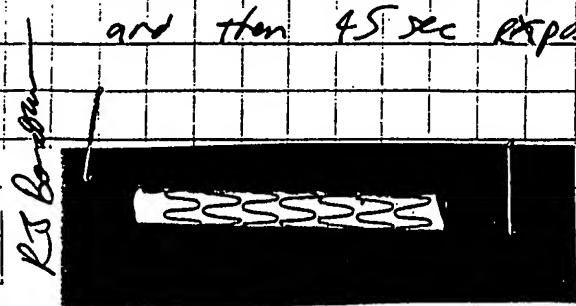
This is done for every bend except those along a spine. Experimentally, this appears to work well. The razor did nick the stent surface and sometimes left strands of connecting material. The operation really requires a wide-field microscope as the strands are too small to see unaided.

A laser/maser may be able to more cleanly cut the slice by melting the laminate perpendicularly.



Then a thin but non-cutting tool could lift the bend up or touch the cut material under it.

An experimental stent was made using the razor technique, 2MM laminate and 300 μ M tubing. The material was bonded in a 680°F salt bath for 1 min 30 sec in packed salt and then 45 sec rinsed. Preliminary observation are promising.



\leftarrow ID 8 or
 \leftarrow 305 μ m²

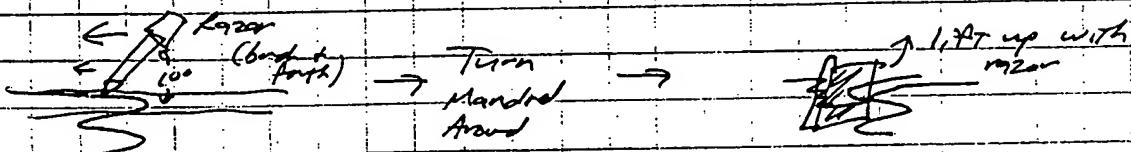
Dept LaminatingJob No.

Tried scraping material off of laminate prior to salt bath.

Method 1-

Scraped material off by holding razor $\sim 10^\circ$ to spent salt bath applying 2 layers of 12 µm PTFE. Instead of "tracing" under with razor at the same time, I did all lamellas in one orientation, turned the mandrel around, lifted each lamella up, then scraped off the material in the other direction, turned the mandrel around, then lifted up the remaining lamellas.

Only a light touch was used in scraping, and I employed a gentle, back-and-forth, gradually advancing motion.



I call this spent 544-7A.

Method 2 - Same as method 1 but without turning the mandrel around and lifting up the lamellas (ie, scraping only). I call this spent 544-7B. Suggested by E. Golds

I bonded these by submerging in a 680°F salt bath for 2'30" in packed salt, then exposed for 45 seconds.

544-7A (material scraped then touched) - material was not bonded on several lamellas. Unclear if this is a problem.

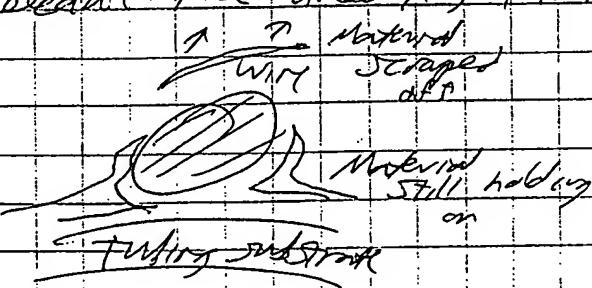
544-7B (not touched) - Material bonded nicely but some lamellas not exposed.

The separation of material @ lamella may be due to the packing technique was to fill the shrink tubing with salt.

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Another design - 6mm sintered I-spine (welded spines not available). Placed over 100µm tubing and covered w/2-layer of 12µM (2µM pore) PTFE + sintered for 2' 95" (680°F). Then, after remove from salt pack & rinsing, I scraped the laminate from the knurled (except at the spine). I found the scraping much easier than with the spines which were scraped pre-sintering. However, attempts to lift the knurled up were frayed because the underlying laminate was now bound to the wire.



Attempts to free the wire caused the laminate to start tearing.

Also, while the laminate scraped off much more easily, it formed small "corkscrews" of material along the edge as the razor passed over.

In call this Stein 544-9, I finished sintering at 45' / 680°F . It was very flexible although the sintered bond wasn't melted. The laminate material was initially attached to the wire, but after some manipulation it melted back up.

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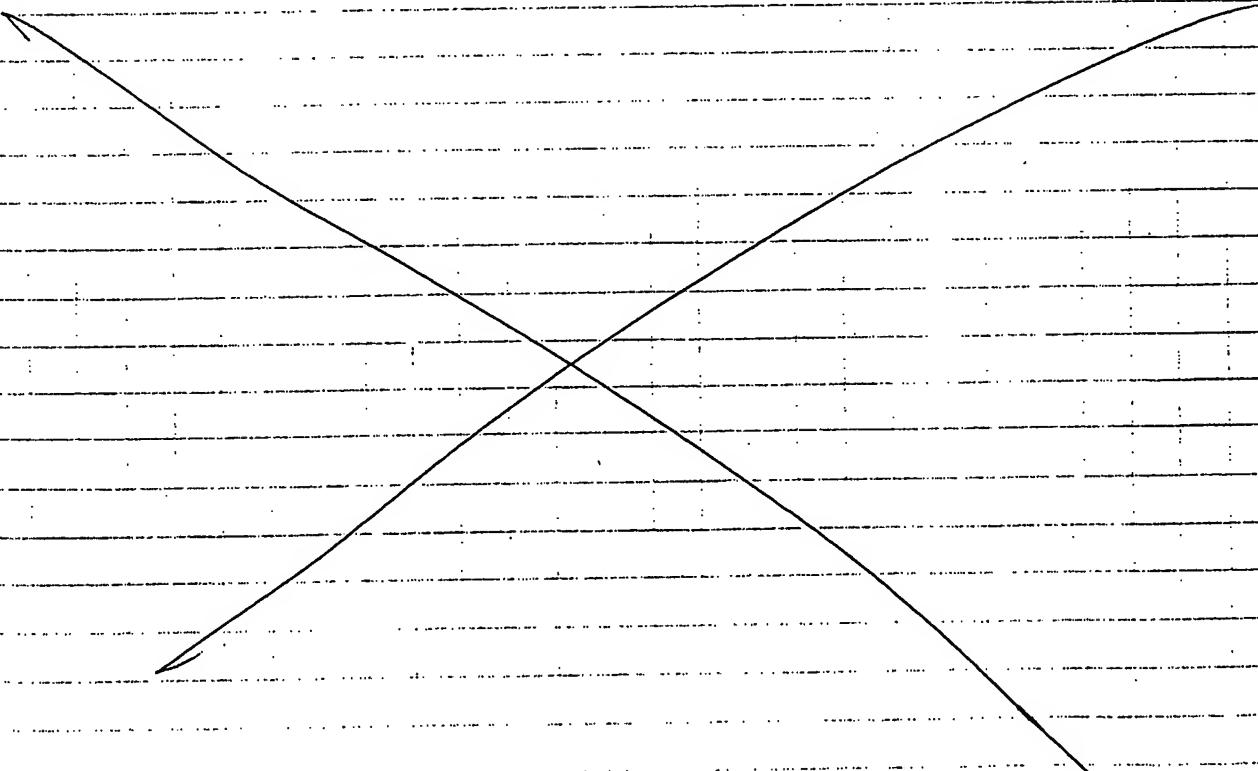
Another design. Prototype deteriorated at 544-10.

Wrapped 9 sintered spent in 2-ply of 12μM PTFE; underneath was a 500% expansion (1200μM) tube. The sutures had all been removed except along the spine; these sutures were reinforced with a drop of cyanoacrylate to duplicate a weld.

Semi-sintered for 75' @ 680°F. The laminate was only marginally sintered; in fact the seam lifted up slightly by running water over the spent. I then scraped off the Luerheller & Todus the material underneath. It was very weak and formed many tiny fibers.

I then packed it in salt, again shrink-wrapped it, shrink-dam the tubing with a heat gun, then shrink-wrapped it a second time. I sintered it for 2' @ 680°F (actual temp ~650°)

The final spent was very flexible but had loose fibers of material on it.



To Page _____

Witnessed & Understood by me,

Date

Invented by

Date

Comparison of Stents

Re No.

Note: these stents were made using hollow steel mandrels.

Objective: to demonstrate at what point during the sintering process it is optimal for uncovering the stent mandrel.

First prototype designated 544-11. Took a 8-hawth (5cm)

sintered stent and glued the suture along the spine, then cut & removed all other sutured. Ultrasonic cleaned in IPA, placed over 500°C expansion (210 μ m) tubing, placed two wraps of 12 μ m stent over it. I then trimmed away the stent over the hawth as per pg 7 method 2, except for hawth along the spine and the first two wraps at either end.

It was extremely difficult to trim back the material as it kept sliding away in particular, extensive manipulation was needed near the seam because the seam kept coming up or bunching up.

I then packed it with salt & heat-shrank the tubing around it. On Bill's suggestion, I let the mandrel cool and then heat-shrank it again.

The second prototype, designated 544-11A, was identical to 544-11 except that it was fully sintered (~600°F / 2'45") before sumping the hawth. Both -11 and -11A were subsequently re-sintered, without the salt pack, for 45 seconds.

The third prototype designated 544-11B, was also the same, but was sintered in salt for 1'20", the hawth scraped, re-packed in salt, re-sintered for 1'20", removed & washed, trimmed, then final heat-salt dipped for 45".

Note: due to non-use of IPA, these stents were removed from mandrel by chilling mandrel & causing it to shrink.

Note: the pre- and during- scraping included "pushing" the material under the stent bends.

Note: Using a hollow mandrel requires great caution during grinding, as the cold water rushing into the hot tube creates flash steam.

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